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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

THE MEDICINES COMPANY,

Plaintiff,

vs.

BIOGEN MA INC. (formerly known as
BIOGEN IDEC MA INC. and
BIOGEN, INC.),

Defendant.

Civil Action No.: 15-cv-_____

COMPLAINT

Plaintiff The Medicines Company ("The Medicines Company"), by and through its counsel, Gibbons P.C., as and for its Complaint against Defendants Biogen MA, Inc. (formerly known as Biogen Idec MA Inc. and Biogen, Inc.) (collectively, "Biogen"), alleges as follows:

SUMMARY OF THE ACTION

On June 22, 2015, the United States Supreme Court affirmed its prior ruling in *Brulotte v. Thys Co.*, 379 U.S. 29 (1964) that United States patent laws "prevent a patentee from receiving royalties for sales made after his patent's expiration." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2406 (2015).

Like in *Brulotte* and *Marvel*, this action is about Biogen -- an overreaching licensor -- which after being paid more than \$800 million in royalties over the past 17 years through expiration of its United States patent on December 15, 2014 -- now seeks unlawfully to extract from The Medicines Company -- its licensee -- yet additional royalties based upon sales that post-date patent expiration. Moreover, here, unlike in *Marvel*, the terms of Biogen's license expressly state that royalties payable upon Net Sales continue only until expiration of the patent. Seemingly, Biogen sees itself unbound by the terms of its own contract and Supreme Court precedent.

In short, under the veil of legal threats and high-handed demands, Biogen is trying to make one last and inappropriate "grab." The Medicines Company, however, has had enough.

Accordingly, The Medicines Company brings this action for breach of contract and declaratory judgments that The Medicines Company has, contrary to Biogen's allegations, threats and demands, satisfied its contractual obligations to a) pay Biogen certain license royalties; and b) provide Biogen reasonable access to The Medicines Company's sales books and records for purposes of validating royalties, and for such other relief as the Court deems just and proper.

THE PARTIES

1. Plaintiff The Medicines Company, at all times relevant to this action, was and is a corporation organized and existing under Delaware law, with its principal place of business located at 8 Sylvan Way, Parsippany, New Jersey 07054.

2. Upon information and belief, Defendant Biogen was and is a corporation organized and existing under Massachusetts law, with its principal place of business located at 14 Cambridge Center, Cambridge, Massachusetts 02142.

3. Defendant Biogen conducts business throughout this judicial district, including business with The Medicines Company that is the subject of this action.

JURISDICTION AND VENUE

4. This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332, because the parties are citizens of different states, and the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interests and costs.

5. This action also arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

6. This Court has personal jurisdiction over Biogen for at least the following reasons: first, Biogen has maintained continuous and systematic contacts with New Jersey and has purposefully availed itself of the privilege of conducting business in New Jersey, including its contractual relationships with parties in New Jersey, such as, for example, The Medicines Company; second, the conduct which gave rise to the claims asserted in this Complaint arose, in whole or in part, in New Jersey; third, Biogen has substantial contacts with New Jersey; fourth, maintenance of this action in this forum will not offend principles of due process; and fifth, Biogen has on many occasions previously submitted itself to the jurisdiction of this Court and/or admitted that this Court has personal jurisdiction over Biogen (e.g., *Andrew Nelson v. Biogen Idec Inc. et al.*, 2:12-cv-7317-MCA-LDW (D.N.J.), *Biogen Idec MA Inc. v. EMD Serono Inc. et al.*, 2:10-cv-2760-CCC-JBC (D.N.J.) and *Bayer Healthcare Pharms. Inc. v. Biogen Idec Inc.*, 2:10-cv-02734-CCC-JBC (D.N.J.)). Furthermore, this Court has specific jurisdiction over Biogen because this action arises out of and relates to Biogen's contacts with The Medicines Company, a New Jersey company, regarding the subject matter of this action.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

FACTS GIVING RISE TO THIS ACTION

8. The Medicines Company is a New Jersey-based, global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace.

9. The Medicines Company markets Angiomax® in the United States and other countries for use in patients undergoing coronary angioplasty.

10. Angiomax® is a direct thrombin inhibitor used as an anticoagulant in patients undergoing coronary angioplasty procedures. Angiomax® is used in the most life-threatening and time urgent percutaneous coronary intervention situations. Over time, it has grown to be the anticoagulant market leader in angioplasties.

11. At one time, United States Patent No. 5,196,404 (the "404 patent"), entitled "Inhibitors of Thrombin," covered The Medicines Company's Angiomax® drug. (Exhibit A)

12. The '404 patent issued on March 23, 1993 and expired on December 15, 2014.

The License Agreement

13. On March 21, 1997, The Medicines Company and Biogen entered into a License Agreement (the "License") under which Biogen granted The Medicines Company an exclusive license to a patent portfolio on a country-by-country basis, including the '404 patent for the United States territory. (Exhibit B) (redacted).

14. Pursuant to the License, The Medicines Company was obligated to pay royalty payments to Biogen based upon The Medicines Company's "Net Sales" of Angiomax®. ("TMC shall pay to Biogen earned royalties on Net Sales of Product sold by TMC.").

15. Royalties due under the License were payable quarterly on Net Sales that accrued during that period.

16. Pursuant to the License, The Medicines Company's obligation to pay royalties based upon Net Sales in the United States ended upon expiration of the '404 patent, *i.e.*, December 15, 2014. To wit, the License states:

The obligation to pay royalties . . . shall continue, on a country by country by country basis, from the date of the First Commercial Sale of Product in a country until . . . the date on which the Product or its manufacture, use or sale is no longer covered by a Valid Claim of any Biogen Patents Rights in such country.

17. In fact, Biogen and The Medicines Company specifically affirmed their understanding that, "[f]or the avoidance of doubt, a sale of Product to ICS or a Wholesaler performing FFS Services that is made on or before December 15, 2014 shall be included in the calculation of Net Sales under Section 1.25 of the License." (emphasis supplied).

18. Many other provisions of the License are consistent with and support this straightforward reading.

19. For seventeen (17) years, The Medicines Company timely and in full met its royalty obligations under the License, paying Biogen in excess of \$800 million in royalties, all without any contribution by Biogen to The Medicines Company's enormous investment in, successful development and growth of its Angiomax® franchise.

20. Naturally, under the License, Biogen was entitled to conduct reasonable audits of The Medicines Company's "books and records containing all particulars relevant to its sales of Products." (emphasis supplied).

21. And, over the course of the 17-year license relationship, The Medicines Company cooperated in responding to reasonable audit requests by Biogen and its outside auditors.

22. Pursuant to Section 10.1 of the License:

[u]pon expiration of TMC's obligation to pay royalties and/or a percentage of Sublicense Royalty Income under Sections 6.3 and 6.5 with respect to a specific country as to which TMC's license is

then in effect, the license shall be deemed to be fully paid and TMC shall thereafter have a royalty-free right to use the Biogen Patent Rights and Biogen Technology to make, have made, use, import, offer to sell and sell Product in such country.

23. Thus, effective December 15, 2014, The Medicines Company acquired a fully paid-up, royalty-free right to “make, have made, use, import, offer to sell and sell” Angiomax® in the United States.

24. In any case, on the date when the '404 patent expired, Biogen no longer had any legal or other right to interfere with The Medicines Company's sales of Angiomax® in the United States. At best, in the event a royalty dispute occurred post-expiration of the '404 patent, Biogen had a right to conduct a reasonable audit of The Medicines Company's sales books and records and, if appropriate, make a damages claim (i.e., bring a collection action) for any alleged unpaid royalties.

25. The Medicines Company has complied and presently is in compliance with all of its obligations to Biogen under the License, including without limitation its obligations to pay royalties to Biogen for sales of licensed product inside and outside of the United States. Moreover, The Medicines Company fully intends to remain in compliance with its License regardless of the pendency of this action.

26. Thus, regardless of any dispute Biogen may now allege regarding certain past royalties allegedly due to Biogen under the License for United States sales, *infra*, Biogen may not use or threaten such alleged unpaid royalties as a basis to interfere in any way with The Medicines Company's a) sales of Angiomax® in the United States; b) rights under the License outside of the United States; and/or c) other rights under the License.

The Royalty Dispute

27. After the '404 patent expired on December 15, 2014, on February 13, 2015, The Medicines Company delivered (from New Jersey) to Biogen its final royalty payment for Net Sales of Angiomax® in the United States.

28. On June 8, 2015, Biogen initiated an audit (in New Jersey) of The Medicines Company's sales books and records for the period January 1, 2012 through December 15, 2014.

29. Throughout the audit, The Medicines Company cooperated with Biogen's auditors, provided the auditors with reasonable access to The Medicines Company's sales books and records, and even responded in writing to specific questions presented by the auditors and provided to the auditors additional supporting documentation in that regard.

30. In the course of the audit, Biogen, through its auditors and then its outside attorneys, questioned and later disputed three (3) matters around The Medicines Company's final royalty payment for the 2014 calendar year.

31. First, for the first time in the parties' 17 year license relationship, Biogen claimed that in addition to royalties on Net Sales of Angiomax®, The Medicines Company also owed royalties for product manufactured by The Medicines Company prior to December 15, 2014 (the expiration date of the '404 patent), if that product was later sold in the United States.

32. The Medicines Company rejected Biogen's new and twisted "post-expiration sale/pre-expiration manufacture" interpretation of the License, and advised Biogen's auditors that it was disputing any additional royalties owed in that regard. For the Medicines Company, it was clear that Biogen's revisionist interpretation of the License was just an inappropriate attempt by Biogen to "grab" whatever more it could extract from The Medicines Company now that the United States license had expired.

33. Further, of course, Biogen's attempts to extract payment of royalties from The Medicines Company based upon United States sales post-dating expiration of the '404 patent would be contrary to the laws and policies of the United States, as noted by, among other courts, the United States Supreme Court in *Brulotte v. Thys Co.*, 379 U.S. 29 (1964) and, more recently, in *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2406 (2015).

34. Second, Biogen questioned the legitimacy of one specific sale of Angiomax® in the United States, dated December 18, 2014, by suggesting that The Medicines Company inappropriately posted the sale after December 15, 2014 to avoid paying Biogen a royalty. Of course, in casting its baseless "conspiracy" theory, Biogen ignored the fact that a) consistent with prior years, on December 15, 2014, The Medicines Company announced an Angiomax® price increase effective January 1, 2015 -- causing customers to book substantial sized orders of Angiomax® in the last two weeks of the calendar year to capture the benefit of the lower price, and b) other sizable sales of Angiomax® were booked on December 15, 2014 and right before December 15, 2014, all of which were captured in additional substantial royalties paid to Biogen for calendar year 2014.

35. The Medicines Company provided all of this documented information to Biogen's auditors. And, here again, The Medicines Company chalked up Biogen's rhetoric to just being another inappropriate attempt to "grab" whatever more it could extract from The Medicines Company now that the United States license had expired.

36. Third, on August 11, 2015, Biogen (this time through its outside counsel) wrote to The Medicines Company (again, in New Jersey) questioning the legitimacy of The Medicines Company's designation for destruction of two batches of Angiomax® material based upon the company's decision that the batches were out-of specification. In essence, Biogen -- as a hands-

off licensor -- attempted to replace its judgment for The Medicines Company's judgment about whether product material was safe to be sold.

37. The Medicines Company debated whether to even respond to Biogen's August 11, 2015 letter, as on its face the letter and its allegations were simply offensive and harassing, and yet another inappropriate "grab" attempt by Biogen.

38. Nevertheless, in its continued spirit of cooperation and compromise, The Medicines Company did respond, explaining to Biogen that one lot of the questioned material was an engineering test batch that was not manufactured for human use or clinical purposes, and that the other lot was deemed rejected by The Medicines Company because of a deviation in the manufacturing protocol. The Medicines Company also provided Biogen additional documentation to support its explanations.

39. As for these second and third issues, like the first, having explained to Biogen all of the surrounding circumstances, The Medicines Company rejected any claim by Biogen that additional royalties were or would be due in that regard.

40. Moreover, The Medicines Company advised Biogen that it had provided reasonably responsive information to each of its inquiries and, from The Medicines Company's perspective, the company considered the matters closed.

41. Nevertheless, Biogen has still persisted. And, Biogen's harassment and threats have now reached a breaking point.

42. On September 15, 2015, Biogen -- again through its outside counsel -- wrote to The Medicines Company (again, in New Jersey) escalating its earlier rhetoric and innuendo by: a) threatening and accusing The Medicines Company of, inter alia, "failing to pay royalties" and now "violat[ing] the implied covenant of good faith and fair dealing;" b) "demand[ing] payment

of the royalties due" and "confirm[ation] that MDCO will revise its quarterly reporting to Biogen."

43. Thus, based upon all of the above circumstances, there are definite and concrete disputes between The Medicines Company and Biogen touching upon their legal relations and respective rights and interests. Further, these disputes are real and substantial, they admit of specific relief through a decree of a conclusive character, and they are of sufficient immediacy and reality to warrant the issuance of declaratory judgments.

44. Such disputes include, inter alia, The Medicines Company's payment of certain royalties to Biogen for United States Net Sales of Angiomax® in calendar year 2014; product manufactured in 2014 that has not been sold in the United States or has been sold since the '404 patent expired on December 15, 2014; certain product designated for destruction by The Medicines Company; and Biogen's audit rights under the License as they relate to these disputes.

45. Further, based upon all of the above circumstances, The Medicines Company has a reasonable apprehension of suit by Biogen regarding each of these disputes.

46. Contrary to Biogen's unfounded allegations, a) the License does not require The Medicines Company to pay to Biogen royalties for product sold in the United States after the '404 patent expired on December 15, 2014 regardless of when such product was manufactured; b) The Medicines Company has fully paid Biogen all royalties due under the License for activities in the United States through December 15, 2014; c) The Medicines Company has acted with good faith and fair dealing and used commercially reasonable efforts to sell Angiomax® in the United States through December 15, 2014; d) The Medicines Company has provided Biogen with reasonable access to its sales books and records regarding sales of Angiomax® in the

United States through December 15, 2014; and e) The Medicines Company is in compliance with all other terms of the License.

COUNT I

(DECLARATORY JUDGMENTS RELATING TO THE LICENSE)

47. The Medicines Company repeats and realleges each and every allegation contained in paragraphs 1 through 46, as if they were fully set forth herein.

48. As detailed above, there exist justiciable controversies between Biogen and The Medicines Company regarding their respective rights and obligations under the License.

49. The Medicines Company is entitled to invoke this Court's power and authority to immediately adjudicate these disputes, and to remove the cloud such disputes have placed over The Medicines Company, each by way of declaratory judgments.

50. Specifically, for the reasons detailed above, The Medicines Company is entitled to declaratory judgments at least as follows:

- a. The Medicines Company is not obligated to pay Biogen royalties on sales of Angiomax® in the United States after December 15, 2014 regardless of when such product was manufactured.
- b. The Medicines Company is not obligated to pay Biogen royalties based only upon manufacturing Angiomax® product and/or Angiomax® product material.
- c. In the event the License is read or interpreted to require The Medicines Company to pay Biogen royalties for sales of Angiomax® in the United States after the '404 patent expired on December 14, 2014, those provisions of the License, as so read or interpreted, are preempted by United States federal law,

run counter to the policy and purposes of United States patent law, and/or are otherwise unlawful under United States law, but do not render the balance of the License invalid or unenforceable.

- d. The Medicines Company is not obligated to pay Biogen any further royalties under the License for past or future sales of Angiomax® in the United States.
- e. The Medicines Company has a fully paid-up, royalty-free right to make, have made, use, import, offer to sell and sell Angiomax® in the United States effective December 15, 2014.
- f. The Medicines Company has complied with its obligations to reasonably make available to Biogen and its auditors information reasonably related to an audit of The Medicines Company's royalty and other obligations under the License regarding United States sales of Angiomax®.
- g. Biogen's threats, accusations and demands regarding The Medicines Company's royalty and other obligations under the License are unsubstantiated, unlawful, and otherwise improper; and Biogen shall immediately cease and desist from making such threats, accusations and demands.
- h. Biogen has no right to interfere with The Medicines Company's, or its commercial partners', sales of Angiomax® in the United States.
- i. The Medicines Company has complied, and presently is in full compliance with its obligations to Biogen under the License.
- j. Biogen has no right to, or threaten to, interfere with, limit, terminate or disturb in any other way The Medicines Company's rights under the License.

- k. Biogen shall honor The Medicines Company's rights under the License, and Biogen shall comply with all of its own obligations under the License.

COUNT II

(BREACH OF CONTRACT BY BIOGEN)

51. The Medicines Company repeats and realleges each and every allegation contained in paragraphs 1 through 50, as if they were fully set forth herein.

52. Pursuant to Section 10.1 of the License, effective December 15, 2014, The Medicines Company acquired a fully paid-up, royalty-free right to make, have made, use, import, offer to sell and sell Angiomax® in the United States.

53. Biogen, by its conduct as described herein, is intentionally interfering with and attempting to cast doubt around The Medicines Company's rights under Section 10.1.

54. By doing so, Biogen has breached its obligations under the License.

55. The Medicines Company has been harmed as a result.

PRAYER FOR RELIEF

WHEREFORE, The Medicines Company prays for judgment and other relief as follows:

1. Declaratory judgments that:
 - a) Under the License, The Medicines Company is not obligated to pay Biogen royalties on sales of Angiomax® in the United States after December 15, 2014 regardless of when such product was manufactured;
 - b) The Medicines Company is not obligated to pay Biogen royalties based only upon manufacturing Angiomax® product and/or Angiomax® product material.

- c) In the event the License is read or interpreted to require The Medicines Company to pay Biogen royalties for sales of Angiomax® in the United States after the '404 patent expired on December 14, 2014, those provisions of the License, as so read or interpreted, are preempted by United States federal law, run counter to the policy and purposes of United States patent law, and/or are otherwise unlawful under United States law, but do not render the balance of the License invalid or unenforceable.
- d) The Medicines Company is not obligated to pay Biogen any further royalties under the License for past or future sales of Angiomax® in the United States;
- e) The Medicines Company has a fully paid-up, royalty-free right to make, have made, use, import, offer to sell and sell Angiomax® in the United States effective December 16, 2014;
- f) The Medicines Company has complied with its obligations to reasonably make available to Biogen and its auditors information reasonably related to an audit of The Medicines Company's royalty and other obligations under the License regarding United States sales of Angiomax®;
- g) Biogen's threats, accusations and demands regarding The Medicines Company's royalty and other obligations under the License are unsubstantiated, unlawful and otherwise improper; and Biogen shall immediately cease and desist from making such threats, accusations and demands;

- h) Biogen has no right to interfere in any way with The Medicines Company's, or its commercial partners', sales of Angiomax® in the United States;
 - i) The Medicines Company has complied, and presently is in full compliance with its obligations to Biogen under the License;
 - j) Biogen has no right to, or threaten to, interfere with, limit, terminate or disturb in any other way The Medicines Company's rights under the License; and
 - k) Biogen shall honor The Medicines Company's rights under the license, and Biogen shall comply with all of its own obligations under the License;
- 2. An award of damages to The Medicines Company, including interest;
 - 3. A preliminary and/or permanent injunction barring Biogen and all Biogen officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from denying, interfering with, limiting, terminating or in any other way disturbing The Medicines Company's rights under the License, and from threatening to do any of the foregoing.
 - 4. A preliminary and/or permanent injunction barring Biogen and all Biogen officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from interfering in any way with The Medicines Company's, or its commercial partners', sales of Angiomax® in the United States, and from threatening to so interfere.
 - 5. An award for reasonable costs and attorney fees in maintaining and defending this

action; and

6. Such other further relief, in law or equity, as this Court deems just and proper.

Respectfully submitted,

GIBBONS P.C.

A handwritten signature in dark ink, appearing to read 'David E. De Lorenzi', is written over a horizontal line.

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